

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TEXARKANA DIVISION

RETRACTABLE TECHNOLOGIES,
INC.,

Plaintiff,

v.

ABBOTT LABORATORIES, INC.,

Defendant.

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CIVIL ACTION NO. 5:05-CV-157 (DF)

ORDER

This case is set on the Court's July 2010 trial docket. Before the Court is Plaintiff's ("RTI's") *Daubert* Motion to Exclude Certain Expert Testimony of Amber Hogan Mitchell. Dkt. No. 121. Also before the Court are Defendant's ("Abbott's") response, RTI's reply, and Abbott's sur-reply. Dkt. Nos. 141, 173, and 191. Having considered the briefing and all relevant papers and pleadings, the Court finds that RTI's motion should be **GRANTED-IN-PART and DENIED-IN-PART**.

I. LEGAL PRINCIPLES

Federal Rule of Evidence ("Rule") 702 requires that any expert be qualified to testify by "knowledge, skill, experience, training, or education":

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise, if

- (1) the testimony is based upon sufficient facts or data,
- (2) the testimony is the product of reliable principles and methods, and

(3) the witness has applied the principles and methods reliably to the facts of the case.

Any such testimony must “assist the trier of fact to understand the evidence or to determine a fact in issue.” *Id.* When faced with a proffer of expert testimony, it is the trial judge’s responsibility to determine, at the outset, whether the expert is proposing to testify to expert knowledge and whether such testimony will assist the trier of fact to understand or determine a fact in issue. *Id.*; *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592 (1993). In this regard, the trial judge acts as a gatekeeper by requiring a valid connection to the pertinent inquiry and assessing “whether the testimony has a reliable basis in the knowledge and experience of [the relevant] discipline.” *Daubert*, 509 U.S. at 592; *Kumho Tire Company, Ltd. v. Carmichael*, 526 U.S. 137, 149 (1999).

Rule 704 provides that “[t]estimony in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact.” The rule is not intended to allow a witness to give legal conclusions and “does not allow an expert to render conclusions of law.” *Snap-Drape, Inc. v. C.I.R.*, 98 F.3d 194, 198 (5th Cir. 1996); *Owen v. Kerr-McGee Corp.*, 698 F.2d 236, 240 (5th Cir. 1983).

II. DISCUSSION

RTI moves pursuant to Rules 702 and 704 of the Federal Rules of Evidence to exclude the testimony of Amber Hogan Mitchell (“Ms. Mitchell”) concerning her opinions relating to compliance with OSHA regulations, patient safety, and market forces and market compliance.

A. Opinions Interpreting OSHA Regulations and the Bloodborne Pathogens Standard

RTI submits that Ms. Mitchell lacks the necessary expertise, training and background to state legal opinions and is not qualified as a legal expert. Dkt. No. 121 at 8. RTI argues that Ms. Mitchell's testimony interpreting OSHA regulations is improper and should be excluded. *Id.* at 7. RTI further argues that Ms. Mitchell does not cite authorities for her legal conclusions but bases her conclusions regarding compliance with the Bloodborne Pathogens Standard ("BPS"), codified at 29 CFR 1910.1030, on her own earlier interpretations of the BPS. *Id.* RTI urges that Ms. Mitchell's opinion "must be based upon something other than her own subjective belief concerning the interpretation of the law to the withstand scrutiny under *Daubert*." *Id.*

Abbott responds that it is "fully appropriate for an expert to present testimony to explain a regulatory scheme." Dkt. No. 141 at 7. Abbott states that Ms. Mitchell is not opining that any party to this case violated a regulation or that the jury should find that any law was violated, but that she is testifying that Abbott had good reason not to sell VanishPoint for use in needleless IV systems. *Id.* at 8. Furthermore, Abbott argues that Ms. Mitchell's discussion of OSHA's enforcement guidelines do not involve matters of "law" because these guidelines are not laws. According to Abbott, "[Ms. Mitchell's] explanation as to how OSHA prioritizes its enforcement actions is based upon her direct experience at the agency and her knowledge of how OSHA allocates its resources." *Id.* at 9.

RTI replies that despite Abbott's description of Ms. Mitchell's testimony as not "opining that any party to this case violated a regulation," Ms. Mitchell "repeatedly opines about facts that

she says would constitute a violation of OSHA regulations.” Dkt. No. 173 at 3. RTI believes that “such testimony consists only of legal conclusions that the Court should exclude from evidence.” *Id.* RTI also argues that Ms. Mitchell improperly offers a legal conclusion when she states in her report that “a recessed needle is inappropriate for a needleless system, and that ECRI’s contrary recommendations ‘contradict regulatory compliance.’” *Id.* at 4. Abbott reiterates in response that “Ms. Mitchell is not opining on any legal issue within the purview of the Court or jury in this case.” Dkt. No. 191 at 1. Abbott argues that it would be more appropriate for RTI to challenge Ms Mitchell’s views on cross-examination. *Id.* at 3.

First, this matter concerns a breach of contract claim brought by RTI. The Court does not find that Ms. Mitchell’s testimony includes her opinions on any legal issue that is to be decided by the jury or this Court. Ms. Mitchell’s testimony also does not state that either party in this matter has violated OSHA regulations. Rather, Ms. Mitchell testimony assists the trier of fact by explaining the BPS and how various systems may or may not comply with this standard. Such testimony is permissible. *Askanase v. Fatjo*, 130 F.3d 657, 673 (5th Cir. 1997); *see also U.S. ex rel Barron v. Deloitte & Touche, LLP*, Civ. No. SA-99-CA-1093-FB, 2008 WL 7136868 (W.D. Tex. Sep. 26, 2008).

Second, RTI does not argue that Ms. Mitchell is unfamiliar with the BPS. RTI’s objection is that Ms. Mitchell bases her opinion testimony on “her own earlier interpretations of the BPS - specifically on an OSHA compliance directive that Ms. Mitchell helped to write and upon letters of interpretation that Ms. Mitchell wrote.” Dkt. No. 121 at 8. According to Ms.

Mitchell's report, Ms. Mitchell was appointed as OSHA's first National Bloodborne Pathogens Coordinator. Dkt. No. 121-1 at 1. In this role, Ms. Mitchell was "responsible for drafting all letters of interpretation on compliance with the BPS for the agency." *Id.* It is reasonable for Ms. Mitchell to base her opinion testimony on letters of interpretation issued by OSHA. It would be unreasonable to prevent Ms. Mitchell from relying on these letters of interpretation merely because she drafted them as part of her responsibilities while employed by OSHA. RTI's arguments go more toward the weight of Ms. Mitchell's testimony than admissibility and would be better addressed during cross-examination. Thus, the Court finds that RTI's motion to exclude Ms. Mitchell's opinions interpreting OSHA regulations and compliance with the BPS should be **DENIED**.

B. Opinions Relating to Patient Safety

RTI submits that Ms. Mitchell lacks the necessary expertise required to give opinions on patient safety and that her opinions on patient safety are not reliable. Dkt. No. 121 at 8. RTI argues that Ms. Mitchell does not have training, nor is she licensed, as a medical doctor, nurse or clinician. RTI argues that Ms. Mitchell's time and experience at OSHA was focused on the safety of health care workers, rather than patients. RTI also states that Ms. Mitchell performed no studies on patient safety with regard to the conclusions in her report, and she testified at her deposition that her conclusions regarding patient safety relied upon her review of the Morbidity and Mortality Weekly Report ("MMWR") which was not identified in her report or its attachments. *Id.* at 9. Additionally, RTI also complains that while Ms. Mitchell testified that she

relied upon articles relating to patient safety, she only reviewed the abstracts of many of these articles. Where an abstract was provided, Ms. Mitchell purportedly only reviewed the abstract. *Id.* at 9-10.

Abbott responds that Ms. Mitchell is “a public health expert, an expert in safety and preventing the spread of bloodborne pathogens, and a regulatory expert who is amply qualified to speak on the subject matter addressed in her testimony.” Dkt. No. 141 at 10. Abbott states that Ms. Mitchell does not conduct a separate analysis relating to patient safety as part of her testimony – “she observes that patient and worker safety are both enhanced by use of needleless systems or potentially compromised by using less safe options.” *Id.* Abbott also points out that Ms. Mitchell is fully accredited in public health, which necessarily relates to the safety of the public. *Id.* According to Abbott, Ms. Mitchell’s work for Becton-Dickinson has involved both patient and worker safety issues and she has reviewed studies on patient safety issues in preparing her expert report. *Id.* at 11.

RTI argues in its reply that Ms. Mitchell’s report does not reflect any expertise in patient safety as opposed to occupational safety. RTI further argues that Ms. Mitchell’s “mere familiarity with these products (which are used on patients)” or her work for Becton Dickinson does not reflect education, training or work history that would qualify her as an expert in patient safety. Abbott does not address RTI’s arguments on this issue in its sur-reply. *See* Dkt. No. 191.

The Court finds that Ms. Mitchell is qualified to testify as an expert on her opinions regarding BPS and patient safety and that RTI’s objections to her testimony goes more to its

weight rather than admissibility. Ms. Mitchell was appointed as OSHA's first National Bloodborne Pathogens Coordinator and had responsibility for training and educating OSHA's Bloodborne Pathogens Coordinators. Dkt. No. 121-1 at 1. There is no indication that her responsibilities as OSHA's BPS Coordinator were only targeted towards healthcare worker safety and did not address patient safety. Ms. Mitchell is also familiar with the availability and conversion to safety devices such as syringes and IV catheters, as well as newly published studies/research related to safety device use. *Id.* In her role at Becton Dickinson, Ms. Mitchell "served as a healthcare worker and patient safety policy analyst and advocate." *Id.* at 2. Thus, the Court finds that Ms. Mitchell has the knowledge and experience to support her testimony. RTI's motion to exclude Ms. Mitchell's opinions regarding compliance with OSHA regulations should therefore be **DENIED**.

C. Opinions Relating to Market Forces and Market Conversion

RTI argues that Ms. Mitchell lacks the necessary expertise required to give opinions on what drives compliance in the market and that her opinions are not reliable. RTI states that Ms. Mitchell does not have training and is not licensed as an economist and has not worked in marketing or selling safety engineered medical devices. Thus, RTI claims, Ms. Mitchell "has no basis to opine on why hospitals make decisions to convert to safety needles or on the scope of the impact that the BPS and the Needlestick Prevention Act have on acute care facilities." Dkt. No. 121 at 10.

Abbott does not address RTI's arguments in its Response, a fact which RTI points out in

its Reply. *See* Dkt. Nos. 141 and 173. In its Sur-Reply, Abbott argues that RTI misrepresents the nature of Ms. Mitchell's opinion. Dkt. No. 191 at 2. Abbott states that Ms. Mitchell explains "the limits of OSHA enforcement, OSHA's limited ability to drive compliance with its regulations, and the fact that conversion to safety syringes is a much lower priority item than other enforcement issues that a hospital must confront" in response to RTI's contention that "hospitals were certain to buy RTI products after 2000 and 2001 because OSHA required use of such products under the 2000 federal needlestick legislation." *Id.* at 3. Abbott argues that it would be more appropriate for RTI to challenge Ms. Mitchell's views on cross-examination. *Id.* at 3.

RTI objects to Ms. Mitchell's opinion that "OSHA regulations . . . do not solely drive market conversion to safety in any industry due to the inability of OSHA to thoroughly enforce and perform inspections in every workplace in every state in the US." Dkt. No. 121 at 10; Dkt. No. 121-1 at 5. In light of her tenure at OSHA and her experience with OSHA regulations, the Court finds that Ms. Mitchell is qualified to testify regarding the limits of OSHA enforcement. However, this does not mean that Ms. Mitchell is qualified to testify regarding the effect that OSHA enforcement has on market forces and market conversion. Ms. Mitchell is being offered as "an expert on sharps safety and the regulatory and scientific environments that encompass sharps safety, including safety needles and needleless systems." Dkt. No. 121-1 at 1. Ms. Mitchell is not being offered as an economics or marketing expert and she does not claim that she has the knowledge, skill, experience, training, or education to claim expertise in those areas.

Thus, the Court finds that RTI's motion to exclude Ms. Mitchell's opinions regarding the effect that OSHA enforcement has on market forces and market conversion should be **GRANTED**.

D. Opinions Based on Ms. Mitchell's Experience in Undisclosed Facilities

RTI argues that Ms. Mitchell should not be allowed to present testimony or opinions based on "anything she observed or did" in various facilities as part of her dissertation. Dkt. No. 121 at 11. According to RTI, Ms. Mitchell testified that one of the basis for her opinion "that a recessed needle was no longer an appropriate use in a needleless system" is her work in various facilities as part of her dissertation. *Id.* Ms. Mitchell has refused to identify the facilities she was in, "claiming that the data that is presented for her dissertation on this level is required to be confidential." *Id.*

Abbott responds that Ms. Mitchell does not merely rely on site visits related to her dissertation as the basis for her opinion that a recessed needle is not appropriately used with a needleless IV system. *Id.* Dkt. No. 141 at 11. Abbott states that Ms. Mitchell is relying on "information from her work at OSHA, her experiences at Becton Dickinson, and more recent work doing her dissertation." *Id.* Abbott further argues that RTI does not show how the names of these hospitals are relevant and that RTI "had a full opportunity to ask Ms. Mitchell about the *substance* of what she had seen or the setting in which she had seen it." *Id.* at 12.

In reply, RTI also reiterates its argument that Ms. Mitchell refused to disclose information about certain clinical settings and deprived RTI of a fair opportunity to cross examine her on that subject. Dkt. No. 173 at 5. Thus, argues RTI, Ms. Mitchell should not be allowed to testify

about her observations in those clinical settings as support for her opinions. *Id.*

Abbott responds to RTI's reply by stating that the facilities Ms. Mitchell visited as part of her dissertation research "are only some of the many, many facilities that Ms. Mitchell has visited, and upon which she relies." Dkt. No. 191 at 3. Abbott submits that Ms. Mitchell did not withhold any information but the names of the facilities she visited for her dissertation research. Abbott further argues that the names of these facilities do not make any difference whatsoever. *Id.* at 3. Abbott also argues that RTI had the opportunity to ask Ms. Mitchell about the details of the various clinical settings that she observed throughout her career and if RTI did not obtain the information, it was because RTI did not ask for it. *Id.* at 3. Finally, Abbott urges that RTI's issues with Ms. Mitchell's testimony are best addressed during cross examination. *Id.* at 4.

RTI objects to Ms. Mitchell's opinion that is based, in part, on her experiences in various facilities that she visited as part of her dissertation because she refuses to disclose which facilities she visited. The Court finds that RTI's objection does not have any merit. RTI only argues that Ms. Mitchell would not disclose the locations she visited, not that she refused to discuss her experiences or observations at those locations. The Court notes that RTI could have sought relief from this Court by filing a motion to compel Ms. Mitchell to disclose this information. However, RTI did not do so. RTI has not shown that Ms. Mitchell's refusal to identify these facilities prevents RTI from probing the basis for her opinions. Furthermore, RTI's arguments go more toward the weight of Ms. Mitchell's testimony than to its admissibility. Thus, the Court finds that RTI's motion to exclude Ms. Mitchell's opinions that are based on her experiences in

facilities she visited as part of her dissertation should be **DENIED**.

CONCLUSION

For the foregoing reasons, RTI's *Daubert* Motion to Limit Testimony of Amber Hogan Mitchell (Dkt. No. 121) is hereby **GRANTED IN PART** and **DENIED IN PART**, as follows:

RTI's request to exclude Ms. Mitchell's opinions interpreting OSHA regulations and the Bloodborne Pathogens Standard is hereby **DENIED**.

RTI's request to exclude Ms. Mitchell's opinions relating to patient safety is hereby **DENIED**.

RTI's request to exclude Ms. Mitchell's opinions regarding the effect that OSHA enforcement has on market forces and market conversion is hereby **GRANTED**.

RTI's request to exclude Ms. Mitchell's opinions that are based on her experiences in facilities she visited as part of her dissertation is hereby **DENIED**.

IT IS SO ORDERED.

SIGNED this 18th day of June, 2010.

A handwritten signature in black ink, appearing to read "David Folsom", is written over a horizontal line.

DAVID FOLSOM
UNITED STATES DISTRICT JUDGE